

#### **REMARKS**

The Office Action of October 19, 2007 has been carefully considered.

Claims 13 and 15 were withdrawn from consideration following the restriction requirement. Claims 13 and 15 have now been amended pending reinstatement should generic claims be found to be allowable.

Regarding the double patenting rejection, Applicant notes its validity, but believes that it would be premature to submit a terminal disclaimer prior to the identification of otherwise allowable subject matter.

Claims 1-12 and 14 have been rejected under 35 USC 103(a) over Cooper et al in view of Chantler.

Cooper et al has been cited for its teaching of spermicidal agents containing cellulosic thickeners, methylparaben antimolding agent, and glycerine or propylene glycol as a hygroscopic agent. Chantler et al has been cited to show the use of chlorhexidine as a spermicide which could be used in the compositions of Cooper et al.

The composition of Cooper et al is stated to be "non-irritating." The problem with such compositions is not that they are irritating; all similar compositions are formulated to be non-irritating.

As Applicant has discovered, the problem with such compositions is that they destroy normal vaginal flora, resulting eventually in fungal infections, which increase the risk of contracting HIV and other diseases. In order to overcome this problem, Applicant teaches adding to the composition "an effective amount of a fungicide to prevent the growth of fungi in the vagina which grow in the absence of natural bacterial flora destroyed by the antiseptic."

Applicant believes that the amount of fungicide necessary to accomplish this result is higher than the amount necessary

to prevent fungal growth in the composition itself. Thus, claims 9, 13 and 14 have been amended to require a minimum of 0.25% methyl paraben, as disclosed in the example at page 10, lines 20 *et seq* of the specification. The upper limit of claim 9, 1.0%, is found in the example at page 9, line 30 of the specification.

In the examples of Cooper et al, the amount of methyl paraben used is 0.1% or 0.2%; see Example 2. This corresponds closely to the amount of methyl paraben used in known commercial compositions such as Predicat™ and K-Y® lubricants, both of which contain 0.1% by weight methyl paraben. The only function of methyl paraben in such compositions is to protect the compositions against fungal growth while in storage.

The larger amount of methyl paraben in the compositions according to the invention enable the compositions to more effectively prevent fungal infections in the vaginal mucosa, *in vivo*, as opposed to merely preserving the compositions while in the container. There is no disclosure or suggestion in the cited art that larger amounts of methyl paraben should be used, since the amounts (0.1-0.2%) disclosed in the references are completely adequate to protect the compositions against fungal growth, and there is no disclosure or suggestion that the methyl paraben should be used for any other purpose.

It is only Applicant who has disclosed an use for a fungicide in a lubricant composition, other than as a preservative. Note the statement at page 13, lines 6-10 of the specification:

"Only compositions 1, 4, 6 and 7 [containing both spermicide and fungicide], were effective in inhibiting the growth of *Candida* in an environment where *Lactobacillus* growth is inhibited. This demonstrates that there is utility to such combinations within genital lubricants designed for intra-

vaginal use."

The utility of such compositions, containing "an effective amount of a fungicide to prevent the growth of fungi in the vagina which grow in the absence of natural bacterial flora destroyed by the antiseptic" is not even remotely suggested by the cited art.

Withdrawal of this rejection is requested.

In view of the foregoing amendments and remarks, Applicant submits that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



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